No. 14802.

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

A. SCHLESSING, claimant of 75 articles of device, more or less, designated as "The Schlessing Ultrasoniseur," together with their labeling,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

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Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

I.

STATEMENT OF JURISDICTION.

Under 21 U.S.C. 334(a) and (d), the District Court had jurisdiction to condemn the devices involved in this appeal, to permit the Claimant to attempt to salvage the condemned devices under conditions which would assure their being brought into compliance with law, and to rule upon the legality of the Claimant's proposed method of distributing such devices.

Under 28 U.S.C. 1291, this Court has jurisdiction to review the decisions of the District Court.

II.

STATEMENT OF FACTS.

The present appeal is an outgrowth of an *in rem* seizure action instituted in the District Court September 5, 1952, by the United States pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) seeking condemnation of 75 devices, more or less, designated as "The Schlessing Ultrasoniseur." [R. 3-7.] Authority for such action stems from 21 U.S.C. 334(a) which provides for condemnation of any device that is adulterated or misbranded when introduced into or while in interstate commerce. The devices had been shipped by A. Schlessing and Co., Inc., from St. Louis, Missouri, to chiropractors practicing in Southern California within the jurisdiction of the District Court. [R. 3, 9.]

The Libel of Information alleged that these devices were misbranded in violation of 21 U.S.C. 352(a) because their labeling bore false and misleading therapeutic claims for many disease conditions ranging from abscesses to ulcers. [R. 4-5.]

The Libel alleged that the devices were further misbranded in violation of 21 U.S.C. 352(a) because their labeling contained such false and misleading statements as "This Machine Is Absolutely Safe"; "No special skill, no involved instructions and no long experience is necessary to use the Schlessing Ultrasoniseur properly"; and "There are no contra-indications. No danger of deep burns, tissue damage or irritation. Equally important, there are no possible harmful effects to the person administering treatment." [R. 5-6.]

The Libel also alleged that the devices were misbranded in violation of 21 U.S.C. 352 (f)(1) because their labeling failed to bear adequate directions for use. [R. 6.]

Finally, the Libel alleged that the devices were adulterated in violation of 21 U.S.C. 351(c) because their strength differed from and their quality fell below that which they purported and were represented to possess, since their ability to produce total sound output differed materially from the ability they were represented to possess, and the output meter did not accurately gauge the energy density output of the devices. [R. 6.]

On October 22, 1952, Mr. A. Schlessing of St. Louis, Missouri, intervened as Claimant in this proceeding. [R. 8.] He is the president of A. Schlessing and Co., Inc., which manufactured these devices. He is also the agent of the owners and consignees of the devices.

Also on October 22, 1952, a Consent Decree of Condemnation was filed in this case. [R. 8-14.] By its terms, the devices under seizure were adjudged adulterated and misbranded as alleged in the Libel and were condemned under 21 U.S.C. 334(a). [R. 9.] In addition, pursuant to 21 U.S.C. 334(d), Claimant was accorded the privilege of attempting to bring the devices into compliance with law under supervision of a duly authorized representative of the Federal Security Administrator [R. 10-13], hereinafter called the Secretary.[1]

One provision in the Consent Decree declares in substance that the Claimant shall not distribute the devices

---

[1]The Federal Security Administrator was then the head of the Federal Security Agency which was charged with the administration of the Federal Food, Drug and Cosmetic Act. On April 11, 1953, pursuant to Reorganization Plan No. 1 of 1953, and 67 Stat. 18, the Federal Security Agency was abolished and the Department of Health, Education, and Welfare was established to administer the functions formerly in that Agency, under the supervision and direction of the Secretary of that Department. (18 Fed. Reg. 2053.)

until he obtains a written release from a representative of the Secretary, and there is a further proviso that

> "Claimant shall make no distribution of said articles or any part of them except in strict accord with such term and conditions as may be included in said written release."

[R. 11, par. (4).] This provision is in line with 21 U.S.C. 334(d) which vests supervisory control over salvaging operations in the Secretary. See *U. S. v. 1322 Cans . . . Black Raspberry Puree,* 68 F. Supp. 881 (N.D. Ohio, 1946).

Claimant thereupon arranged to ship the 47 devices actually seized by the United States Marshal, back to his place of business at St. Louis, Missouri, where 6 of them were reconditioned from a physical standpoint to the satisfaction of the Department of Health, Education, and Welfare. [R. 18.] Reconditioning of the remaining 41 devices has been suspended until a final decision is reached regarding the legality of Claimant's proposed method of distribution of the 6 reconditioned devices. [R. 18.]

Claimant's proposal was to ship the 6 reconditioned devices back to the licensed California chiropractors in whose possession these devices were seized at the outset of this proceeding. [R. 19.] The Department refused to release the devices for such distribution. [R. 19.]

It is agreed by the parties that these ultrasonic devices produce high frequency sound waves which have therapeutic value in the treatment of osteoarthritis and bursitis. [R. 20-23.] It is also agreed [R. 19, par. (5)]:

> "Ultrasonic therapy cannot be employed safely and efficaciously by the layman in self-medication, but requires competent supervision in its administration.

> Adequate directions for unsupervised lay use cannot be written for ultrasonic devices, within the meaning of 21 U.S.C. 352 (f)(1). Interstate distribution which would not violate the Federal Food, Drug, and Cosmetic Act must therefore comply with the regulations which exempt devices from bearing adequate directions for use in their labeling. (21 C.F.R. §1.106, as amended.) One provision of these regulations exempts a device which is shipped to *'a practitioner licensed by law to * * * use or direct the use of the device.'* (21 C.F.R. §1,106(e))."

The Department's refusal to release the reconditioned devices for distribution in the manner proposed by Claimant was based upon its view that California chiropractors are *not licensed by law to use or direct the use of ultrasonic devices.* [R. 19-20, par. (6).] Consequently, shipment of the devices to the chiropractors would not meet the conditions of the exemption regulations.[2] Since the devices would not bear adequate directions for use in their labeling as required by 21 U.S.C. 352(f)(1), and would not be exempt from that requirement, they would be misbranded.

In the Consent Decree of Condemnation, the District Court had expressly retained jurisdiction "to issue such further Decrees and Orders as may be necessary to the proper disposition of this proceeding." [R. 13.]

---

[2]In addition, paragraph (7) of the Consent Decree of Condemnation declares [R. 12]:

> "The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug and Cosmetic Act, *or the laws of any State * * * in which they are sold or disposed of.*"

On May 24, 1954, Claimant filed with the District Court a Motion to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure. [R. 27-29.] The Motion asserts that the Department's refusal to approve was based upon an erroneous interpretation of the scope of a license granted under the California Chiropractic Act.

On February 10, 1955, the District Court filed an Order denying Claimant's Motion and giving Claimant 90 days to submit any other proposal for distribution to the Department. [R. 49-50.] On the same day, the District Court also filed Findings of Fact and Conclusions of Law. [R. 40-49.]

On April 7, 1955, Claimant filed a Notice of Appeal from the District Court's Order of February 10, 1955. [R. 51.]

On May 17, 1955, the District Court filed a Final Order directing Claimant to return the devices to the United States Marshal, and directing the Marshal to offer the devices for sale under conditions to be specified by the Department. [R. 51-53.]

Also on May 17, 1955, on Stipulation by the parties, the District Court filed an Order which stayed execution of the Final Decree during the pendency of this appeal, said Order also reducing the performance bond and permitting the removal of the devices to a warehouse. [R. 54-55.]

On May 27, 1955, Claimant filed a second Notice of Appeal, this time from the Final Decree of May 17, 1955.

III.

QUESTIONS PRESENTED.

(1) Does Claimant's proposal that the 6 reconditioned ultrasonic devices be shipped to chiropractors licensed and residing in California, satisfy the requirements of 21 C.F.R. §1.106(e) so as to exempt the devices from bearing adequate directions for use in their labeling, as required by 21 U.S.C. 352(f)(1)?

(2) Was the District Court clearly in error in its finding of fact that a chiropractor who is licensed under the laws of California is not authorized to use or direct the use of the ultrasonic devices under seizure in this case?

IV.

PERTINENT STATUTES AND REGULATIONS.

21 U.S.C. 334 (a).

> "Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against . . . on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . ."

21 U.S.C. 352.

> "A drug or device shall be deemed to be misbranded—
>
> "(a) If its labeling is false or misleading in any particular."
>
> * * * * * * *
>
> "(f) Unless its labeling bears (1) adequate directions for use; . . . *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public

health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

21 U.S.C. 351.

"A drug or device shall be deemed to be adulterated—

* * * * * * *

"(c) If . . . its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

21 U.S.C. 334 (d).

"Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may . . . direct . . .; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided,* that after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary . . ."

21 Code of Federal Regulations Sec. 1.106 (e).

"Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use.

". . . a drug or device shipped directly to or in the possession of a practitioner licensed by

law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from section 502 (f)(1) of the act [21 U.S.C. 352 (f)(1)] if it meets the conditions of paragraphs . . . (d)(2) and (3) of this section."

21 Code of Federal Regulations Sec. 1.106.

"(d) *Exemption for prescription devices*

"A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared, shall be exempt from section 502 (f)(1) of the act [21 U.S.C. 352 (f)(1)] if all the following conditions are met:

* * * * * * *

"(2) The label of the device (other than surgical instruments) bears:

"(i) The statement 'Caution: Federal law restricts this device to sale by or on the order of a .....,' the blank to be filled in with the word 'physician', 'dentist,' 'veterinarian,' or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

"(ii) The method of its application or use.

"(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use . . ."

California Chiropractic Act of 1922.

West's Annotated California Codes, Business and Professions, Section 1000 ff, page 45 ff.

Deering's California Codes Annotated, Business and Professions, Vol. 2, Appendix, page 519 ff.

[Note: Appellant has printed this Act as an appendix to his opening brief.]

V.

SUMMARY OF ARGUMENT.

A. Introduction.

The ultrasonic devices in question have value in the treatment of some conditions. However, they cannot be used safely and efficaciously by the layman without professional supervision. Therefore, "adequate directions for use" cannot be written for these devices as required by 21 U.S.C. 352(f)(1), but they may be exempt from this requirement if they comply with the conditions of exemption.

One condition of exemption is that the devices be shipped to "a practitioner licensed by law . . . to use or direct the use of the device." Since Claimant has proposed to ship the reconditioned devices to California chiropractors, the fundamental issue is whether a license issued under the California Chiropractic Act authorizes its holder to use ultrasonic devices in his practice of chiropractic.

B. Scope of Authority of California Chiropractors.

(1) Definition of Problem.

Under the California Chiropractic Act, a licensee is authorized (1) to practice chiropractic as taught in chiropractic schools or colleges, and (2) to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body, but not to practice medicine.

It is therefore necessary to determine (1) whether ultrasonic therapy is part of the practice of chiropractic as taught in chiropractic schools or colleges, and (2) whether ultrasonic therapy is a necessary mechanical measure incident to the care of the body which does not constitute the practice of medicine.

This case calls for interpretation of a California law. There are two reported opinions of the Appellate Department, Superior Court, Los Angeles County which, if binding on this Court, would dispose of the appeal in favor of the Government. Under criteria announced by this Court, those opinions would not be binding. The Court may choose to restate those criteria. On the other hand, if the appeal is decided on the merits, the State Court decisions would at the least be highly persuasive.

(2) Is Ultrasonic Therapy Part of the Practice of Chiropractic as Taught in Chiropractic Schools or Colleges?

Chiropractic is a system for the practice of adjusting the joints, especially at the spine, *by hand,* for the treatment of disease and ailments. This was the connotation of chiropractic in 1922 when the California Chiropractic Act was adopted, and it remains the authoritative definition of chiropractic today. Amendments of this Act and legislative enactments in other fields have not changed the scope of authority of a licensed California chiropractor.

Many subjects other than chiropractic are taught in chiropractic schools but it is only *chiropractic* as taught in those schools that a licensed chiropractor is authorized to practice.

In the early 1920's, chiropractic schools taught "adjunct" methods of healing such as electrotherapy and hydrotherapy but these methods were candidly recognized as not being chiropractic.

Ultrasonic therapy is not a part of *chiropractic* as taught in chiropractic schools or colleges.

(3) Is Ultrasonic Therapy a Necessary Mechanical Measure Incident to the Care of the Body Which Does Not Constitute the Practice of Medicine?

Section 7 of the Chiropractic Act authorizes a licensee to use necessary mechanical, hygienic and sanitary measures incident to the care of the body which do not invade the field of medicine and surgery.

Section 7 does not authorize use of a mechanical measure if it is part of the practice of medicine. Only a *chiropractic* mechanical measure such as a chiropractic table is authorized.

Ultrasonic therapy is used by medical doctors in the treatment of their patients and is a part of the practice of medicine.

C. Unsuccessful Attempts to Amend the California Chiropractic Act Substantiate View That Authority of Licensed Chiropractor Is Narrowly Limited.

Failure to adopt proposed amendatory legislation does not provide a binding interpretation of the Act but may be considered by the Courts.

An Initiative Proposal in 1939 to amend the Chiropractic Act would have broadened a licensee's authority by permitting him (1) "to diagnose and treat diseases, injuries, deformities, or other physical or mental conditions," and (2) to use any type of diagnostic or treating measure other than drugs or surgery. Chiropractors who opposed this measure stated it would "authorize chiropractors to practice medicine under chiropractic licensure."

The Proposal was rejected at the polls.

D. Miscellaneous Points.

(1) The Burden of Proof Is Upon Appellant.

Since the Appellant seeks an exemption from the statutory requirement that the labeling of the devices bear adequate directions for use, he has the burden of showing compliance with the conditions of exemption.

Here he must show that the chiropractors to whom the devices are to be shipped are licensed by law to use or direct the use of the devices.

(2) The Federal Food, Drug, and Cosmetic Act Is an Instrument of Public Protection.

The Federal Food, Drug, and Cosmetic Act is designed to protect the public health and pocketbook, and is construed so as best to effectuate that objective.

CONCLUSION.

Since Appellant has not established that California chiropractors are licensed by law to use the ultrasonic devices in question, distribution to such persons would violate the Federal Food, Drug, and Cosmetic Act.

The judgment of the District Court should be affirmed.

VI.

ARGUMENT.

A. Introduction.

Ultrasonic therapy is a relatively new addition to the armamentarium of the physician in his combat against disease. As is true of so many other "miracle" drugs and devices, enthusiasts and promoters of this therapy hastened to proclaim it as virtually a panacea and minimized or completely overlooked its potential hazards. Such premature,[3] extravagant, and ill-considered representations are not in the public interest. Representations of this type were in part the basis for the initial proceeding against the devices here in question. [R. 4-6.]

Claimant thereafter revised the labeling for the devices under seizure to eliminate unwarranted claims and misleading representations. [R. 18, par. (3).] The Department of Health, Education, and Welfare has no objection to this labeling. It is a matter of concern to the Department, however, that devices of this type should be used only by qualified persons in treating the public.

The Federal Food, Drug, and Cosmetic Act requires that the labeling of a device bear adequate directions for use [21 U.S.C. 352 (f)(1)], and a proviso of that section authorizes the Secretary to promulgate regulations which exempt devices from such requirement when "not necessary for the protection of the public health." Such

---

[3]Competent investigators are constantly exploring and appraising the potential of ultrasonic therapy for good and bad. In Exhibit A attached to the Stipulation of Facts [R. 22, footnotes 2, 3 and 4], there are listed a few references to articles in American scientific publications on the medical uses of ultrasound. The titles of these articles alone suggest the scope and significance of the work which has been done and is yet to be done in this field.

exemption regulations have been promulgated. [21 C.F.R. §1.106(b) *et seq.*] Where, as is here agreed, adequate directions cannot be written for safe and efficacious lay use without professional supervision, the device may be exempt from the "adequate directions for use" requirement only if the conditions of exemption are met. See *U. S. v. El-O-Pathic Pharmacy, et al.,* 192 F. 2d 62, 75 (C.A. 9, 1951).

One condition in the exemption regulations is that the device be shipped to "a practitioner licensed by law . . . to use or direct the use of the device." [21 C.F.R. §1.106(e).] It would of course be possible for the Secretary to promulgate exemption regulations under Section 352 (f) which would disregard State licensing laws and set up independent federal qualifications that would have to be met by the practitioner to whom the device is shipped before there could be any exemption. But the pattern of the Federal Food, Drug, and Cosmetic Act and the regulations involved in this case give full faith and credence to the licensing laws of each State and do not seek to superimpose a federal licensing system in the field of the healing arts. This regulatory plan is reasonable and in furtherance of the recognition of each State's authority over internal matters.

For these reasons, and since Claimant wished to ship the devices to California chiropractors, the principal issue before the District Court was whether a chiropractor practicing under the Chiropractic Act of California is licensed to use ultrasonic devices such as those under seizure. The District Court found that ultrasonic therapy is not a part of the practice of chiropractic, that it is a part of the practice of medicine, and that a chiropractor licensed under the laws of California is not authorized to use or direct

the use of the ultrasonic devices under seizure in this case. [R. 45-46.]

On appeal, the ultimate question is whether these findings of the District Court are clearly erroneous. [Rule 52(a), Federal Rules of Civil Procedure.]

B. Scope of Authority of California Chiropractors.

(1) Definition of Problem.

The authority of a California chiropractor stems from the Chiropractic Act, an initiative measure approved in 1922. [West's Annotated California Codes, Business and Professions, Section 1000 ff, page 45; Deering's California Codes Annotated, Business and Professions, Vol. 2, Appendix, page 519.] Section 7 of that Act reads:

> *"Certificate to Practice*
>
> "One form of certificate shall be issued by the board of chiropractic examiners, which said certificate shall be designated 'License to practice chiropractic,' which license shall authorize the holder thereof to practice chiropractic in the State of California as taught in chiropractic schools or colleges; and, also, to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body, but shall not authorize the practice of medicine, surgery, osteopathy, dentistry, or optometry, nor the use of any drug or medicine now or hereafter included *in materia medica.*"

The restrictive nature of the chiropractor's authority is emphasized by a comparison with the statutory authority granted to physicians and surgeons. Deering's California Codes Annotated, Business and Professions, Vol. 1, §2137, provides:

> *"Practice authorized by certificate: Physician's and surgeon's certificate.*
>
> "The physician's and surgeon's certificate authorizes the holder to use drugs or what are known as medical preparations in or upon human beings and *to sever or penetrate the tissues of human beings* and *to use any and all other methods* in the treatment of diseases, injuries, deformities, or other physical or mental conditions." [Emphasis added.]

The scope of the "practice of medicine" is broad, broad enough to encompass anything done by a chiropractor. But the Chiropractic Act has carved out a limited area within which it is legitimate for a chiropractor to operate. His authority, however, is only that which is expressly conferred by Section 7 of that Act—namely:

(1) to practice *chiropractic* as taught in chiropractic schools or colleges, and

(2) to use all *necessary mechanical,* and hygienic and sanitary *measures incident to* the care of the body, *but* not to practice medicine, surgery, osteopathy, dentistry, or optometry, and not to use any drug or medicine included *in materia medica.*

Thus, the principal problem resolves itself into two parts:

(a) Is ultrasonic therapy part of the practice of chiropractic as taught in chiropractic schools or colleges?

(b) Is ultrasonic therapy a necessary mechanical measure incident to the care of the body which does not constitute the practice of medicine?

Obviously, this Court is being called upon to interpret provisions of a law of the State of California. A number

of courts of that State have already interpreted those provisions in the manner we are urging here, as we will point out in our subsequent argument. This Court has announced criteria as to the circumstances under which interpretations of California law by California State courts will be binding upon this Court. *State of California, Department of Employment v. Fred S. Reynauld & Co., Inc.*, 179 F. 2d 605 (C.A. 9, 1950). On page 609, the Court stated:

> "We think the rationale of Erie R. Co. v. Tompkins, 1938, 304 U.S. 64 . . . and King v. United Commercial Travelers, 1948, 333 U.S. 153 . . . is that federal courts are bound (a) when the supreme judicial tribunal of the state has decided a given question, or (b) a state appellate court which is in the line of the state appellate structure leading up to the supreme tribunal of the state has decided it, or (c) a goodly number of the trial courts of the state generally and for a considerable period of time have adhered to a common interpretation of the point."

Two California decisions were cited as binding in the *Reynauld* case. One was an *unreported* decision of the Appellate Department, Superior Court, San Francisco County, and the other was an *unreported* decision of the trial department, Superior Court, San Francisco County. This Court declared that neither decision fell within any of the above-quoted categories. Other factors were also present. On page 608, footnote 4, the Court said:

> "That we are here concerned with a statutory provision written into California law verbatim from a federal statute is a further inducement for our con-

sideration of the case on its merits . . . Apparently no federal court has had occasion to construe the federal statute in these circumstances."

In the present appeal, this Court is asked to interpret a California Initiative Act which is not patterned after any federal statute. Two *reported* California decisions which we will later discuss more fully, both by the Appellate Department, Superior Court, Los Angeles County, are dispositive of this appeal in favor of the appellee if they are binding on this Court. *People v. Fowler,* 32 Cal. App. 2d (Supp.) 737, 84 P. 2d 326 (1938); *People v. Mangiagli,* 97 Cal. App. 2d (Supp.) 935, 218 P. 2d 1025 (1950).[4] As we will show, every reported California decision (including those of District Courts of Appeal and the Supreme Court) which has touched upon the meaning

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[4]The *Fowler* case has been cited with general approval of its rulings on chiropractic by a California District Court of Appeal. and by several of the highest courts of other states:

People v. Nunn, 65 Cal. App. 2d 188, 194, 150 P. 2d 476, 480 (Dist. Court of Appeal, Second Dist., Div. 2, 1944);

State v. Moore, 117 P. 2d 598, 604 (Supreme Court of Kansas, 1941)—speaks of the *Fowler* case as a "well-considered decision";

Lynch v. State, 145 P. 2d 265, 270 (Supreme Court of Washington, 1944);

State v. Wagner, 297 N. W. 906, 910 (Supreme Court of Nebraska, 1941);

Smith v. State Board of Medicine, 259 P. 2d 1033, 1038 (Supreme Court of Idaho, 1953).

The latter case also cites the *Mangiagli* case. In *California Procedure,* Vol. 1, p. 247 (1954), Witkin says of reported memorandum opinions of the Appellate Department, Superior Court:

"The total number of such reported opinions is not large, but their coverage is extensive. Since they often deal with questions which do not reach the higher reviewing courts, they are of considerable value and are freely cited by the Supreme Court and district courts of appeal."

of chiropractic or the scope of chiropractic licensure, has expressed views in harmony with the *Fowler* and *Mangiagli* cases.[5] Two attempts made to amend the Chiropractic Act in a manner that would overcome the restrictive effect of the *Fowler* and *Mangiagli* cases, have been defeated at the polls.

We have briefly mentioned the California decisions and the conformity doctrine at the outset of our argument so that the Court will be alerted to their underlying significance here. The Court after full consideration may choose to decide the case on the merits or may elect to restate the views it expressed in the *Reynauld* case *supra* so as to make the *Fowler* and *Mangiagli* cases binding in this appeal.

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[5]Appellant cites the unreported case of *Purviance v. Brockman* (Trial Department, Superior Court, Amador County, No. 4284, 1939). [Appellant's Opening Brief, p. 41.] This appears to be the only California case which suggests that a chiropractor may use hydro-therapy, electro-therapy, heat, and enemas. There is, of course, nothing even in that case about ultrasonics. As far as our research has disclosed, with the exception of the *Purviance* case, California unreported cases which have considered the question have uniformly ruled that chiropractic consists solely of manual adjustment and does not include such modalities as electrode treatment or radionic treatment:

People v. Arnold Morris Lovaas (Superior Court, Orange County, C5240, May 26, 1942);

Credit Bureau of San Jose v. Josephine DePonzi (Superior Court, Santa Clara County, No. 77390, July 2, 1951);

McGranahan v. Berger et al. (Superior Court, San Francisco County, No. 257,362, October 6, 1938).

In the *Credit Bureau* case, the Court ruled that radionic treatments which "caused high frequency radionic waves to enter the patient with either stimulating or relaxing effects" were not authorized under Section 7 of the Chiropractic Act. In the present case, we are dealing with high frequency sound waves which penetrate the body and may affect tissues of the body located inches below the surface. [R. 18-19, par. 4.]

(2) Is Ultrasonic Therapy Part of the Practice of Chiropractic as Taught in Chiropractic Schools or Colleges?

The meaning of the term "chiropractic" is fundamental to the consideration of this appeal. It was found by the trial court that—

> "Chiropractic is a system for the practice of adjusting the joints, especially at the spine, by hand, for the treatment of disease and ailments." [R. 45.]

In an analogous case, the same court had earlier expressed a similar viewpoint. *U. S. v. 22 Devices . . . Halox Therapeutic Generator,* 98 F. Supp. 914, 918 (S.D. Calif., 1951). In both instances, the court relied upon interpretations of California State courts, particularly *People v. Fowler,* 32 Cal. App. 2d (Supp.) 737, 84 P. 2d 326 (Appellate Department, Superior Court, Los Angeles County, 1938).

The *Fowler* case is the most exhaustive California decision as to what constitutes the practice of chiropractic as authorized by Section 7 of the Chiropractic Act. Declaring that the words of a statute must be taken in the sense in which they were understood at the time when the statute was enacted [32 Cal. App. 2d (Supp.) 746], the Court quotes extensively from dictionaries, encyclopedias, Corpus Juris, and court cases that were current in 1922 when the Chiropractic Act was adopted. [32 Cal. App. 2d (Supp.) 745-747.] On page 746, the Court said:

> "In *State v. Hopkins* (1917), 54 Mont. 52 [166 Pac. 304, 306, Ann. Cas. 1918D, 956], the court quoted from Webster's New Standard Dictionary this definition of 'Chiropractic': 'A system of [or] the practice of adjusting the joints, especially of the spine, by hand for the curing of disease.' "

* * * * * * * *

"Nor has the accepted meaning of 'chiropractic' since changed, for in the latest (1938) edition of Webster's New International Dictionary we find the same definition quoted in *State v. Hopkins, supra* . . ."[6]

And on page 747, the Court added:

"The court's instruction defining 'chiropractic' in the words already quoted from Webster's New Standard Dictionary was correct."

In a later case, the same Court emphatically reaffirmed the holdings in the *Fowler* case. *People v. Mangiagli,* 97 Cal. App. 2d (Supp.) 935, 218 P. 2d 1025 (Appellate Dept., Superior Court, L. A. County, 1950). On page 938, the Court said:

"The legal problems presented here are substantially identical with those considered in *People v. Fowler* . . . This court discussed there at some length the construction of the several statutes above mentioned and their effect on each other, and without repeating all that was said we approve of and adhere to it."

* * * * * * * *

"This matter was discussed in the *Fowler* case, *supra,* where we held that section 7 authorized, by the provision numbered as [1] above, nothing that was not chiropractic, as that term was understood in 1922, when the act was passed, and that the term was then defined as 'a system of [or] the practice of adjusting the joints, especially of the spine, by hand for the curing of disease.' "

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[6]The 1955 edition of Webster's New International Dictionary, Unabridged, defines chiropractic as:

"A system, or the practice, of adjusting the joints, esp. of the spine, by hand for the curing of disease."

In *Quail v. Industrial Accident Commission of California,* 138 Cal. App. 412, 417, 32 P. 2d 402, 404 (Dist. Ct. of Appeal, Calif., 3rd Dist., 1934), the Court stated:

> "The term 'Chiropractic' is defined as a system of curing disease by means of adjusting the joints of the spine by hand."

The earliest California case which discusses the definition of chiropractic is that of *Ex parte Greenall,* 153 Cal. 767, 96 Pac. 804 (1908). There the Supreme Court did not state its own view but simply repeated the definition advanced by counsel. On page 769, the Court said:

> "We are informed in the briefs that the word 'chiropractic' means a treatment somewhat analogous to that of osteopathy, the removal of the cause of disease without the use of drugs or any other means except the adjustment of the vertebra of the spine by manipulating them with the hand."

In the Dictionary of American Biography, there is a sketch of the founder of chiropractic, Daniel David Palmer, which includes the following statements:

> "The name chiropractic was suggested for the new science by the Rev. Samuel H. Weed of Bloomington, Ill., an early patient. The name (Greek *cheir,* hand, and *praktikos,* efficient) was freely translated by Palmer as 'done by hand'."

The Courts of other states have expressed views similar to those of the California Courts in defining the authority of chiropractors as limited to adjustments by hand. Note especially the two opinions in *State v. Boston,* 278 N. W. 291 and 284 N. W. 143 (Sup. Ct. of Iowa, 1938 and

1939), where the defendant, a chiropractor, was enjoined (278 N. W. at 293) among other things

> "from the use of physiotherapy, electrotherapy, colonic irrigation, colon hygiene, ultra-violet rays, infra-red rays, radionics machines, traction tables, white lights, cold quartz ultra violet light, neuroelectric vitalizer, electric vibrator, galvanic current and sinusoidal current . . ."

The Iowa statute applicable in the *Boston* case defines chiropractors as:

> "Persons who treat human ailments by the adjustment by hand of the articulations of the spine or by other incidental adjustments."

This definition is more specific than that in Section 7 of the California Chiropractic Act, but it is noteworthy that the Iowa Supreme Court said of the Iowa statute (284 N. W. at page 144):

> "The statutory definition does not vary to any great extent from the well-known and generally accepted definition of this form of the healing art."[7]

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[7]For similar holdings in other states, see also: *People v. Ring,* 275 Ill. App. 214, 217 (Ill. Appellate Court, Fourth Dist., 1934); *State Board of Medical Examiners v. McHenery et al.,* 69 So. 2d 592, 596 (Court of Appeals, Louisiana, 1953); *Commonwealth v. Zimmerman,* 108 N. E. 893, 894-5 (Supreme Court, Mass., 1915); *Joyner v. State,* 179 So. 573, 575-6 (Supreme Court, Miss., 1938); *Bakewell v. Kahle,* 232 P. 2d 127, 128 (Supreme Court, Mont., 1951); *State Board of Medical Examiners v. Grossman,* 48 A. 2d 700, 702 (Supreme Court, N. J., 1946), aff'd 52 A. 2d 699 (N. J. Court of Errors and Appeals, 1947); *People v. Johnerson,* 49 N. Y. Supp. 2d 190, 194-5 (Kings County Court, N. Y., 1944); *Nicodeme v. Bailey,* 243 S. W. 2d 397, 399 (Court of Civil Appeals, Texas, 1951); *Board of Medical Examiners v. Freenor,* 154 Pac. 941, 942 (Supreme Court, Utah, 1916); *Walkenhorst v. Kesler,* 67 P. 2d 654, 658, 662 (Supreme Court, Utah, 1937); *State v. Houck,* 203 P. 2d 693, 698 (Supreme Court, Wash., 1949).

Appellant quotes from the laws of several other States in an effort to show that "chiropractic" does not have a uniform meaning throughout the country. [Appellant's Brief 49-51]. We are here concerned with the meaning of language used in a California Initiative Act. The legislature of one State may of course define a term differently from that of another. We have made no effort to compile the statutes relating to chiropractic in those States which authorize its practice. But in examining the statutes which Appellant cites, together with their legislative history, we have noted several points which clearly support our position in this appeal.

The statutory pattern shows that chiropractic laws were adopted in some states in the 1910s and 1920s. These laws were highly restrictive and limited chiropractic to manipulation by hand. Subsequently, chiropractic groups have endeavored to obtain legislation which would broaden the scope of their authorized practice. In some instances they have been successful. In California, they have not as we will discuss in detail in Part C of this argument.

In Arizona, practice is still limited to adjustment "by hand." [Appellant's Brief 49.] This statute was enacted May 18, 1921. [Session Laws of Arizona, 1921, page 262, section 6(c).] An initiative measure "to provide for the improvement of the practice of chiropractic" was defeated in 1932. [See 1933 Session Laws of Arizona, page 614.]

Appellant's Brief, page 50, quotes the Nevada law as amended on March 28, 1955. But the Nevada law as adopted on February 19, 1923, declared:

> "Chiropractic is defined to be the science of palpating and adjusting the articulations of the human spinal column by hand only. This definition is inclusive, and any and all other methods are hereby de-

cleared not to be chiropractic." [Nevada Compiled Laws 1929, Vol. 1, Sec. 1084.]

In 1949, the Nevada statute was amended to provide for two types of licenses—chiropractic and chiropractic-physiotherapy. [Nevada Compiled Laws Supplement 1943-1949, page 60, section 1084.] The definition of "chiropractic" continued to limit that practice to palpation and adjustment "by hand only." A broader definition was adopted for the separate practice of "chiropractic-physiotherapy." Finally in 1955, the law was again amended as cited by Appellant.

Similarly with respect to the Idaho law, Appellant's Brief (page 50) cites the statute as it was amended in 1937. [Session Laws of Idaho, 1935-1937, Section 6, pages 277-278.] But as it was originally adopted on March 11, 1919, it did not authorize a licensee to adjust "displaced tissue of any kind or nature" or to "practice physiotherapy, electrotherapy, hydrotherapy, as taught in chiropractic schools and colleges." [Session Laws of Idaho 1919, page 538, Section 11.]

The Ohio statute quoted on page 51 of Appellant's Brief does not define "chiropractic" but lists it as a separate limited branch of medicine to be regulated by the state medical board. Other branches separately listed are mechanotherapy, electrotherapy, and hydrotherapy, indicating a legislative recognition that chiropractic does not include the others.

Throughout Appellant's Brief, the term "adjunct therapy" is frequently used with the suggestion that "chiropractic" includes manipulation by hand and all other methods which a chiropractor may deem an "adjunct" to hand manipulation. The Chiropractic Act does

not use this term in defining the scope of a licensee's practice. In Webster's New International Dictionary Unabridged, Second Edition, 1955, the word "adjunct" is defined as—

> "Something joined or added to another thing, but not essentially a part of it."

This definition seems most appropriate here.

On page 37 of his brief, Appellant candidly states his concept of chiropractic:

> ". . . chiropractic is the maintenance of structural and functional integrity of the nervous system as being the cause of disease and . . . the practice of chiropractic consists of the use of any and all techniques and means to remove nerve interference at any place in the body including the vertebrae."

This viewpoint, however, was at one time incorporated almost verbatim in a regulation of the Board of Chiropractic Examiners and declared void in *People v. Mangiagli,* 97 Cal. App. 2d (Supp.) 935, 943, 218 P. 2d 1025, 1030 (Appellate Dept., Superior Ct., L. A. County, 1950). In that case a licensed chiropractor was convicted of violating the medical practice act and the conviction was affirmed on appeal. Defendant then filed a petition for rehearing urging the validity of the regulation. Rejecting this argument, the Court stated:

> *Page 943*
>
> "In his petition for rehearing defendant asserts that our decision cannot stand because it is in conflict with a regulation of the Board of Chiropractic Examiners adopted October 22, 1949, defining chiropractic thus: 'The basic principle of chiropractic is the maintenance of the structural and functional integrity of the nervous system. The practice of chiro-

practic consists of all necessary means to carry out these principles.' . . . The conflict between this regulation and the meaning of 'chiropractic' as defined in our opinion herein, and in *People v. Fowler* . . . is fairly obvious. Under this regulation a licensed chiropractor might very well engage in a great variety of medical and surgical practice; indeed, it would be difficult to discover any sort of treatment of the sick or afflicted that could not, by a little ingenuity, be brought within it. But this does not cause us to doubt the correctness of our decision; it leads us, rather, to the conclusion that the regulation is void."

That regulation has been reworded so that it now reads:

"The basic principle of chiropractic is the maintenance of structural and functional integrity of the nervous system. The *practice of chiropractic consists of the use of any and all subjects enumerated in Section 5* and referred to [in] any and all other sections of the act." [California Administrative Code, Title 16, Sec. 302(a).]

Section 5 of the Chiropractic Act enumerates the minimum educational requirements for a chiropractor. When the Act was adopted in 1922, the following was the complete list of subjects specified in Section 5:

Anatomy
Histology
Elementary chemistry and toxicology
Physiology
Bacteriology
Hygiene and sanitation
Pathology
Diagnosis or analysis
Chiropractic theory and practice
Obstetrics and gynecology. [Calif. Stats. 1923, p. XC.]

PHYSIOTHERAPHY WAS NOT LISTED.

In 1947, however, as Appellant points out on pages 58 and 63 of his brief, Section 5 of the Act was amended to include physiotherapy. [Calif. Stats. 1947, ch. 151, p. 678.] Since the current regulation quoted above defines the practice of chiropractic to consist of the use of all subjects enumerated in Section 5, the argument apparently is that a chiropractor may now utilize physiotherapy in his practice.

A related argument was made and rejected in *People v. Mangiagli, supra,* 97 Cal. App. 2d (Supp.) 935, 939, where the Court said:

> "In other words, the limits of permissible practice by the holder of a chiropractic license, as fixed by section 7 of the statute, do not extend, under the provision we have numbered [1], beyond the scope of chiropractic as that term was understood and defined in 1922, and the ambitious attempts of chiropractic schools or colleges to extend them by teaching other subjects under the guise of chiropractic must fail, so long as the statute remains as it is now. *The statute has been amended by a proposal made by the Legislature in 1947* (Stats. 1947, pp. 676-680), and approved by popular vote; *but these amendments so made have not changed section 7 of the act,* and we find nothing in the changes of other sections which affects or alters the meaning of section 7." [Emphasis added.]

Manifestly, it is the expressed judicial view that Section 7 of the Chiropractic Act, which alone deals with the scope of a chiropractor's authority under that Act, may not be enlarged by indirection. Consequently, the use of physiotherapy does not become a part of the practice of chiropractic simply because it is included in the chiropractic curriculum.

Another oblique argument is advanced by Appellant on pages 44-45 of his brief where he cites *Oosterveen v. Board of Medical Examiners,* 112 Cal. App. 2d 201, 246 P. 2d 136 (Dist. Ct. of Appeal, Second Dist., Div. 3, Calif., 1952) and suggests that the Court approved the use of electricity by chiropractors for healing purposes. (Parenthetically, ultrasonic therapy is not electricity.) Actually, in footnote 1 of the opinion, the appellate court set forth verbatim the trial court's definition of "Naturopathy" which includes the use of electricity. The Court then went on to say (pp. 205-206) that the use of *natural* methods of healing may be employed by physicians and surgeons, osteopaths, chiropractors, and all those who hold licenses as drugless practitioners. But on page 209, the Court observed:

> "When we speak of the right to use the methods commonly employed by naturopaths, *we do not adopt the trial court's definition of naturopathy in all respects.* Some of the practices mentioned might in some circumstances be regarded as the use of drugs or medicine, which, of course, is prohibited to chiropractors." [Emphasis added.]

We submit that the *Oosterveen* case is not helpful to the Appellant's position.

Appellant's brief (pages 38-41) refers to recently enacted statutes governing physical therapy and through some tortuous argument arrives at the conclusion that chiropractors are authorized to practice all types of physical therapy. The irrelevance of these statutes to the present issue is clearly stated in the following quotation

from 23 Opinions California Attorney General 179, 181 (1954):

> "The Chiropractic Initiative Act was not amended by the legislative enactment of [the physical therapy statutes], since no initiative measure can be amended except by vote of the electors unless otherwise provided in said initiative act (Calif. Constitution, Art. IV, Sec. 1), and there is no provision for legislative amendment in the Chiropractic Act. *The enactment of the two Physical Therapy Statutes in 1953 neither increased nor decreased the scope of the practice of chiropractic. To the same extent that a chiropractor could practice physical therapy before the 1953 legislation, it follows that such practice of physical therapy still is within the scope of the chiropractic license,* and that to engage in *such* practice of physical therapy a chiropractor need not be registered . . . or licensed . . . [under the Physical Therapy Statutes.]" [Emphasis added.]

Adjustment by hand for the treatment of disease is one form of physical therapy, but the licensed chiropractor need not comply with the new physical therapy statutes in order to continue giving manual adjustments.

Section 7 of the Chiropractic Act authorizes the holder of a license issued thereunder "to practice *chiropractic* in the state of California *as taught in chiropractic schools or colleges.*" It is only *chiropractic,* as taught in chiropractic schools, that he may practice.

In the case of *In re Hartman,* 10 Cal. App. 2d 213, 51 P. 2d 1104 (Dist. Ct. of Appeal, Fourth Dist., Calif., 1935), the Court said of Section 7 (at page 217):

> "While the section contains the additional clause 'as taught in Chiropractic schools or colleges,' the entire

section must be taken as a whole and it cannot be taken as authorizing a license[e] to do anything and everything that might be taught in such a school. A short course in surgery or one in law might be given, incidentally, and it would not follow that the section would then authorize a licensed chiropractor to engage in such other professions. It is not sufficient that a particular practice is taught in such a school. Under the terms of the statute *it must meet the further test that it is a part of chiropractic, whatever that philosophy or method may be, and, further, that it shall not violate the provision which expressly forbids the practice of medicine.* If such a practice is not a part of chiropractic but does constitute the practice of medicine, it is not authorized under this license even though it may be taught in such a school." [Emphasis added.]

These views were further amplified in *People v. Fowler, supra,* 32 Cal. App. 2d (Supp.) 737, where the Court said on page 747:

"The effect of the words 'as taught in chiropractic schools or colleges' is not to set at large the signification of 'chiropractic,' leaving the schools and colleges to fix upon it any meaning they choose. Were the word 'chiropractic' of unknown, ambiguous or doubtful meaning, this clause, 'as taught' etc., might serve to provide a means of defining or fixing its signification, but there is here no such lack of clarity. The scope of chiropractic being well known, the schools and colleges, so far as the authorization of the chiropractor's license is concerned, must stay within its boundaries; *they cannot exceed or enlarge them* . . . If our opinion in *People v. Schuster* (1932), 122 Cal. App. (Supp.) 790, 795, is thought to go farther than this, we now qualify it in that respect,

deeming the rule just stated to be the proper one." [Emphasis added.]

Note *U. S. v. 22 Devices . . . Halox Therapeutic Generator,* 98 F. Supp. 914, 918; and *People v. Mangiagli,* 97 Cal. App. 2d (Supp.) 935, 939.

Appellant relies on three affidavits of chiropractors. [Appellant's Brief, pages 29-33.] The tenor of these affidavits is that the affiants went to chiropractic colleges in California during the early 1920s, and that those colleges taught electrotherapy, hydrotherapy, and other physical modalities during that period. Each affiant asserts in substance that these fields were within the scope of chiropractic as it was understood at that time. [R. 29-37.]

Obviously, such assertions are conclusions rather than facts. Moreover, the Exhibits which are appended to the affidavits[8] demonstrate that these assertions are *contrary to fact.* These Exhibits unequivocally show (1) that chiropractic meant manipulation by hand and (2) that electrotherapy, hydrotherapy, etc., *were* taught but as a part of a *different* system of healing, namely, *Naturopathy.*

A few excerpts from *Exhibit C* attached to Dr. Houde's affidavit will substantiate this statement. *Exhibit C* is the Annual Announcement of the Los Angeles College of Chiropractic for 1921-1922:

Page 17

"Chiropractic is the science of locating the cause of disease, and the art of removing it by *spinal adjust-*

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[8]By Stipulation, these Exhibits were not printed but are presented to the Court for consideration in this appeal in their original form. [R. 73-74.]

ments, thereby relieving impingements on the spinal nerves.

"The word Chiropractic is derived from two Greek words, Cheir meaning *hand,* and Praktikos meaning *practice.*"

Page 19

"The successful treatment of the nervous system means the successful treatment of practically all diseases, *and this the Chiropractor does with the knowledge of the surrounding structures and his skillful hands.*"

Page 21

"The spine is the foundation of health . . . If the nerve is abnormal the organ controlled by it is abnormal. *Every nerve in the body* can be reached directly or indirectly and *can be treated manually* . . . It is the sole purpose of the Chiropractor to re-establish the proper anatomical relation between the nerves and the surrounding structures."

Page 33

"We make our students master of Chiropractic *and every other form of treatment.*"

Pages 35-36

"Naturopathic Methods—Chiropractically Considered

". . . Millions of people are abandoning drugs and turning to natural methods of treatment. Chiropractic is the one supreme and all-important method. *Dr. Cale, the president of our college, uses nothing but pure, specific, unalloyed Chiropractic* with his private patients. He needs nothing else . . . He believes implicitly in straight Chiropractic.

"Then you might ask, why do we teach electricity, hydrotherapy and the other Naturopathic methods?

> The answer is very simple. We teach them because we want our graduates, *in addition to being thoroughly competent in Chiropractic,* to be as competent in the use of electricity as the best electrotherapist, to be as competent in the use of hydrotherapy as the best hydrotherapist . . . In other words, *we want our graduates to know all that the best Chiropractors know,* and *in addition* to know all that the *other* fellows know. Ignorance is no virtue. Chiropractors will more quickly discover the *utter uselessness of 'adjuncts' and 'mixing'* if they use them awhile than if they are left in ignorance of them." [Emphasis added.]

From the last sentence quoted, it is obvious that the college considered Naturopathic methods to be not only independent of Chiropractic methods, but also inferior. Rarely, we submit, is the body of an affidavit so completely demolished by an Exhibit which it appends.

The "Course of Instruction" which appears on page 4 of the same *Exhibit* lists "Chiropractic Theory and Practice" separately from "Naturopathic Methods," and includes only under the latter such subjects as "Hydrotherapy" and "Electrotherapy." Many other subjects listed on that page are expressly prohibited to a chiropractor by Section 7 of the Chiropractic Act.

Dr. Hotchkiss appends to his affidavit as *Exhibit B* a 1920 brochure of the Eclectic College of Chiropractic. The concept of chiropractic entertained by this College was the same as that of the Los Angeles College of Chiropractic. However, the Eclectic College did not dis-

parage the methods of the other healing arts which it taught. A few excerpts will support these statements:

Inside of cover page

"The Eclectic College . . . (holds) full authority . . . to teach, practice and demonstrate *Chiropractic and its allied Therapeutics* . . ."

Page 1

". . . a school that would teach *Chiropractic as fundamental but* that would not limit its course of training to a *single* branch of Natural Healing."

Page 2

"Therefore, Chiropractic has come to mean *'adjustment with the hands,'* and *it gives a clear insight into the method involved in the practice of this great modern healing agency* . . ."

Page 10

"The Eclectic idea of including *all* of the valuable and important systems of drugless treatment, *in addition to the regular Chiropractic course of study,* marks a great advance in the art of equipping the up-to-date Chiropractic Physician." [Emphasis added.]

It is true that the course of study required of applicants for the chiropractic license by Section 5 of the Chiropractic Act and by regulations of the Board of Chiropractic Examiners covers a wider area than the scope of a license issued under Section 7 of that Act. Dr. Norcross on page 2 of his affidavit states that examinations for chiropractic licenses have at all times included questions on the theory and practice of physio-

therapy. But this is no criterion as to the scope of a license issued under Section 7.

In *Georgia Ass'n of Osteopathic Physicians and Surgeons, Inc., et al. v. Allen,* 31 F. Supp. 206 (M.D. Georgia 1940), aff'd 112 F. 2d 52 (C.A. 5, 1940), the Court had occasion to consider various Georgia statutes relating to practitioners of the healing arts. It was the Court's holding in forceful language that the breadth of an examination does not determine the scope of a license to practice. On page 213, the Court said:

> "A chiropractor is examined in anatomy, physiology, symptomatology, pathology, physical diagnosis, neurology, chemistry, hygiene and sanitation, chiropractic orthopedy, nerve tracing and adjusting, as taught in chiropractic schools. His license, however, authorizes only the adjustment of patients. (84-509.) *His knowledge must be broader than his practice; he must know what he practices but may not practice all he knows.*" [Emphasis added.]

Similarly, speaking of osteopaths on the same page, the Court stated:

> "However, the license authorized by 84-1209 does not necessarily include everything embraced in the examination . . . *It may be necessary for an osteopath to know numerous subjects in order to make a diagnosis and to determine whether osteopathic treatment or some other treatment is indicated. He should know when not to give an osteopathic treatment.*" [Emphasis added.]

See also *State v. Wagner,* 297 N.W. 906, 910 (Supreme Ct. of Nebraska, 1941); *People v. Ratledge,* 172 Cal. 401, 405, 156 Pac. 455 (1916).

Appellant quotes extensively from the book "Principles and Practice of Spinal Adjustment" by Arthur L. Forster (1915) [Claimant's Exhibit B] in an effort to show that more was taught *as chiropractic* in the California colleges of chiropractic than manipulation by hand. [Appellant's Brief 15-16, 34-37.] Affidavits on which Appellant relies assert that this volume was used as a textbook in the early 1920s at the Los Angeles College of Chiropractic and the Eclectic College of Chiropractic. [R. 31, 33, 36.] We have already shown how narrow was the concept of "chiropractic" in those colleges which taught *other methods* in addition to chiropractic. Forster's volume also advocated the use of *other methods in addition to* chiropractic. But he, too, recognized that chiropractic itself is manipulation by hand. Thus on page 1, paragraph 1, he said:

> "Chiropractic (G. *cheir,* hand, and *praktikos,* efficient) is the art and science of treating disease by the adjustment of displaced vertebrae, thereby relieving impingement of the nerves passing through the intervertebral formina."

And on page 315, paragraphs 1 and 2, he said:

> "Briefly defined, spinal adjustment is the replacement to their normal position of subluxated vertebrae for the purpose of relieving pressure upon the nerves . . .
>
> *"This replacement of subluxated vertebrae is accomplished by the application of a definite thrust by the hands of the operator in contact with the affected vertebra."* [Emphasis added.]

Other textbooks cited by Appellant (Brief, pp. 17-19) are not in the Record here.

There are four colleges of chiropractic in California, three of which have never taught ultrasonic therapy.[9] The fourth college does teach ultrasonic therapy as a part of several courses; in that college, such teaching was first introduced in 1946, many years after approval of the Chiropractic Act in 1922.

The trial court found that while ultrasonic therapy is taught in one chiropractic college in California, it is not a part of the practice of chiropractic. [R. 45.] The trial court also found:

> "A subject does not become a part of the practice of chiropractic merely because it is taught in a chiropractic college. Many subjects are taught in Chiropractic colleges which are not part of the practice of chiropractic." [R. 45-46.]

Thus jurisprudence is also taught in the California colleges of chiropractic [See Appendix A, this brief, par. 4] but it can hardly be argued that the chiropractor may for that reason practice law.

We submit that the trial court did not err in finding that ultrasonic therapy is not a part of *chiropractic* as taught in chiropractic schools or colleges. As we will establish in the next part of this brief, ultrasonic therapy actually is a part of the practice of medicine.

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[9]See Supplemental Stipulation as to Facts, pars. (1)-(3). This Supplemental Stipulation was designated for printing [R. 73, par. 8] but does not appear in the printed transcript of record. We have therefore printed it as Appendix A in this brief.

(3) Is Ultrasonic Therapy a Necessary Mechanical Measure Incident to the Care of the Body Which Does Not Constitute the Practice of Medicine?

Section 7 of the Chiropractic Act which defines the scope of a licensee's authority is divided into two parts by a semicolon. The second part states:

> "and, also, to use all *necessary mechanical,* and hygienic and sanitary *measures incident to the care of the body, but shall not authorize the practice of medicine* . . ."

In this connection, the trial court made two significant findings [R. 46]:

> "Ultrasonic therapy is not a necessary mechanical measure incident to the care of the body in the practice of chiropractic."
>
> "Ultrasonic therapy is a part of the practice of medicine."

Webster defines the term "incident" as "naturally happening or appertaining, esp. as a subordinate or subsidiary feature." This seems to be the connotation adopted for the term by the California Courts.

In the case of *In re Hartman,* 10 Cal. App. 2d 213, 51 P. 2d 1104 (Dist. Ct. of Appeal, Fourth Dist., Calif., 1935), the defendant chiropractor contended that the use of hypodermic instruments to administer the Koch cancer treatment was authorized by Section 7. Rejecting this argument, the Court said at page 217:

> "We think this cannot be held to be *merely* a measure incident to the care of the body within the meaning of that section, both because that clause of the section refers to general hygienic and sanitary measures, even though mechanical, *and not to the*

treatment of diseases and ailments, and because the section contains the further limitation that the authorization granted shall not extend to the practice of medicine or surgery." [Emphasis added.]

In *People v. Nunn,* 65 Cal. App. 2d 188, 150 P. 2d 476 (Dist. Ct. of App., Second Dist., Div. 2, 1944), the Court said (at page 194) of a chiropractor licensed under Section 7:

"He may not invade the field of medicine or surgery or administer drugs or medicines included within *materia medica. He is limited to the use of mechanical measures incident to the care of the body which do not invade the field of medicine and surgery.* (People v. Fowler, 32 Cal. App. (2d) Supp. 737.)" [Emphasis added.]

In *People v. Fowler,* 32 Cal. App. 2d (Supp.) 737, 749-750, 84 P. 2d 326, 332-3 (Appellate Dept., Superior Ct., L. A. County, 1938), the Court carefully considered the "incidental measures" authorized by Section 7 and declared at page 750:

"But the other 'measures' mentioned in Section 7 are described in such general terms that they might well include many things which would be a part of medicine or surgery in the stricter sense . . . As to such measures, the proviso [against the practice of medicine] has an apparent office to perform; it prevents the chiropractor from resorting to them by authority of his license as such, or, as the trial court put it, he cannot 'invade the field of medicine and surgery.' [Nor] . . . does the statute confer any selective function upon chiropractic schools or colleges. They cannot, by teaching any measures which are properly a part of the practice of medicine . . . prevent them from being such, or authorize chiropractors to make use of them."

Clearly, only a *chiropractic* mechanical measure, such as a chiropractic table, would be permissible under Section 7. The Section does not authorize use of a mechanical measure if it is a part of the practice of medicine.

To argue that the ultrasonic devices in question are necessary *chiropractic* mechanical measures would be to overlook a fundamental tenet of chiropractic—namely, that chiropractic is a system for the practice of adjusting the joints, *especially at the spine.* Yet ultrasonic therapy is improper for use directly over the spinal column. [R. 26.]

More significant, however, is the fact that ultrasonic therapy is a part of the practice of medicine:

> "Medical doctors, particularly those who specialize in physical medicine, employ ultrasonic therapy, where medically indicated, as part of their regular treatment of their patients." [Supplemental Stip. As To Facts, Appendix A of this brief, paragraph (5).]

This stipulation is further corroborated in Claimant's Exhibit A entitled "The Effect Of Single And Multiple Treatments Of New Zealand White Rabbits With A Schlessing Ultrasoniseur" which includes the following statement as its concluding paragraph on page 8:

> "It is the opinion of the investigators that, if directions are followed, the use of the Schlessing Ultrasoniseur does not represent a dangerous therapeutic procedure and can safely be employed by qualified individuals *in the practice of physical medicine.*" [Emphasis added.]

Note also the medical journal articles cited in the Record, page 22, footnotes 2, 3, and 4.

The Court will recall that a physician's and surgeon's certificate authorizes the holder, among other things, *"to sever or penetrate the tissues of human beings."* [Section 2137, Business and Professions Code.] This authority, being a part of the practice of medicine, is denied to the chiropractor.

In *People v. Fowler, supra,* 32 Cal. App. 2d (Supp.) 737, the Court stated on pages 749-750:

> ". . . we conclude that the words 'medicine,' and 'surgery,' as used in section 7 of the Chiropractic Act, were intended to continue as to chiropractors the limitations imposed on drugless practitioners by the Medical Practice Act, that is, *to deny them* the use of drugs and medical preparations and *the severing or penetrating of the tissues of human beings."* [Emphasis added.]

But the ultrasonic devices in question produce high frequency sound waves which *do penetrate* the body and may affect tissues located inches beneath the surface. [R. 18-19, par. (4).] In the use of these devices, "a moderate amount of energy is inducted into the tissue and bony structures"; there is "good beaming and good depth of penetration of sound waves"; "energy [is] absorbed to a greater extent in muscle than in fat"; and there is "selective heating at the tissue-bone interfaces." [R. 20-22.]

This type of penetration of the tissues is accomplished with sound waves rather than with surgical instruments, and it creates its own peculiar hazards.

> ". . . it is of the utmost importance that treatments be given by a doctor thoroughly familiar with the potentialities of the apparatus inasmuch as there is always the possibility of tissue damage from the reflective qualities of ultrasound by causing localized over-heating of bone and muscle when the energy rays are concentrated too long in one place." [R. 21.]

Note also the contraindications, that is, the conditions where ultrasound therapy would be improper or undesirable. [R. 26.]

There would appear to be ample reason for a holding such as that in *O'Neill v. Board of Regents, etc.,* 74 N. Y. Supp. 2d 762 (Supreme Ct., Appellate Div., 1947), appeal dismissed 83 N.E. 2d 469 (1948), where the Court stated at page 763:

> "Physiotherapy in its general sense is 'the treatment of disease by physical remedies rather than drugs' and *its practice is the practice of medicine* in that limited field." [Emphasis added.]

See also *Joyner v. State,* 179 So. 573, 576 (Supreme Court, Miss., 1938), 115 A.L.R. 954, for a holding that the use of surgical instruments, electrical instruments, and "other appliances" in the treatment of disease is a part of the practice of medicine and surgery.

We submit that the trial court did not err in finding that "ultrasonic therapy is not a necessary mechanical measure incident to the care of the body in the practice of chiropractic" and that "ultrasonic therapy is a part of the practice of medicine."

C. Unsuccessful Attempts to Amend the California Chiropractic Act Substantiate View That Authority of Licensed Chiropractor Is Narrowly Limited.

Since the enactment of the California Chiropractic Act in 1922 by initiative, there have been several direct attempts to enlarge the scope of a chiropractor's authority through amendment of the Act by initiative propositions. (Proposition 9 in 1934 and Proposition 2 in 1939.) Neither amendment was adopted. Both measures were supported by one group of chiropractors and opposed by another group of chiropractors, as appears in the arguments submitted to the voters.

Failure to adopt amendatory legislation does not provide a binding interpretation of the Act sought to be amended, though apparently it is a factor which may be considered by the Courts. See *Fahey v. O'Melveny & Myers, etc.,* 200 F. 2d 420, 479 (C.A. 9, 1952); *California Toll Bridge Authority v. Kuchel,* 40 Cal. 2d 43, 53-54, 251 P. 2d 4 (1952); 82 C.J.S. §360, pages 790-791.

The 1939 Initiative Proposal would have made fundamental revisions in the Chiropractic Act. Thus it would have changed Section 7 to read:

> "One form of certificate shall be issued by the board of chiropractic examiners; said certificate shall be designated 'License to practice chiropractic,' which license shall authorize the holder thereof to diagnose and treat diseases, injuries, deformities or other physical or mental conditions of human beings, without the use of drugs and without in any manner severing any of the tissues of the human body."

Under this proposal, the only limitation upon the licensed chiropractor would have been the use of drugs and surgery. It should be borne in mind that by this time (1939), the California Courts had judicially demarcated the narrow scope of Section 7. See cases cited earlier in this brief, especially *Fowler* (1938), *Quail* (1934), and *In re Hartman* (1935).

If this proposal is compared with Section 7 of the Chiropractic Act, the attempted enlargement of the licentiate's authority is obvious. Instead of being licensed to practice "chiropractic" he would have been authorized "to diagnose and treat diseases, injuries, deformities, or other physical or mental conditions." Instead of being restricted to the use of measures "incident to the care of the body" with a proviso against "the practice of medicine, surgery, osteopathy, dentistry, or optometry," he would have been permitted to use any type of diagnostic or treating measure other than drugs and surgery.

The rather brief argument offered to the voters *in favor of* the 1939 Amendment said little about the enlarged scope of authority to practice. The following excerpts are taken from that argument:

> "In 1922 the people of California voted to give Chiropractors a license to practice, and since that time no change has been made in this law. Times and conditions now make it necessary that the changes asked for in this amendment be added to the present law.
>
> * * * * * * * *
>
> "PROHIBITS THE USE OF DRUGS OR SURGERY BY CHIROPRACTORS."

The argument *against* the proposed 1939 Amendment, like the one in favor of it, was submitted by a group of three chiropractors.[10] We quote a few excerpts from that argument:

> "The present California Chiropractic Act, adopted by the people in 1922, provides for the legal practice of chiropractic, in connection with which the chiropractor may use *'all necessary measures' incident to the practice of chiropractic.* . . .
>
> *"The proposed amendment would authorize chiropractors to practice medicine under chiropractic licensure.* The proposed increase in hours of study is in subjects not designed to increase the student's knowledge of Chiropractic or his ability to practice it. . . .
>
> "Today, the chiropractic field is divided into two groups. One group includes those chiropractors who have adequate education and training *in chiropractic,*

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[10]The argument against this proposed amendment was submitted by:

T. F. Ratledge, D.C.,
Chairman Legislative Committee,
California Chiropractic Association.

L. A. McLellan, D.C.,
Secretary Chiropractic League of California.

Roy G. Labachotte, D.C.,
President of Palmer Standardized Chiropractors of California.

The argument in favor of this proposed amendment was submitted by:

Stanley M. Innes,
Past President, Affiliated Chiropractors of California.

George E. Swanson,
President, Affiliated Chiropractors of California,
Alameda-Contra Costa Unit.

W. F. Morris,
Member, State Board of Chiropractic Examiners.

> and therefore, sincerely believe in its efficacy and completeness as a true science of health and who are *happy to leave medical practices to those who are fully educated, trained and authorized by law to practice medicine.* The other group includes a conglomerate of chiropractic licentiates whose chiropractic education is nondescript and inadequate, and who, therefore, never came to seriously believe in chiropractic principles nor in their own ability to apply them in practice. Also in this group are those whose only interest in possessing a chiropractic license is to use it as a shield behind which they hope to engage in illegal practices and escape the penalties for such violations of law." [Emphasis added.]

These statements were made by *chiropractors* and are clearly in conformity with the views enunciated in the early 1920's by the Los Angeles College of Chiropractic and the Eclectic College of Chiropractic regarding the connotation of "chiropractic."

We submit that these unsuccessful efforts to amend the Chiropractic Act substantiate our position that the practice of chiropractic is narrowly limited and that California chiropractors are not licensed by law to use the ultrasonic devices in question.

D. Miscellaneous Points.

(1) The Burden of Proof Is Upon Appellant.

Appellant seeks to establish that his proposed shipment of the devices in question to California chiropractors entitles those devices to an exemption from the affirmative requirement of 21 U.S.C. 352(f)(1) that their labeling

bear adequate directions for use. It is a settled rule of law that where a statute defines an offense and then creates an exception, he who seeks to show that he comes within the exception has the burden of proof. *People v. Fowler,* 32 Cal. App. 2d (Supp.) 737, 743 (1938); *Ocean Accident & Guaranty Corp. v. Rubin,* 73 F. 2d 157, 166 (C.A. 9, 1934), 96 A.L.R. 412; *McKelvey v. U. S.,* 260 U.S. 353, 357 (1922).

And such an exception is narrowly construed so as not to include any case which does not clearly fall within its provisions. *U. S. v. Dickson,* 15 Pet. 141, 165 (1841); *Canadian Pacific Ry. Co. v. U. S.,* 73 F. 2d 831, 834 (C.A. 9, 1934); *Shilkret v. Musicraft Records,* 131 F. 2d 929, 931 (C.A. 2, 1942), cert. den. 319 U.S. 742; *Ryan v. Carter,* 93 U.S. 78, 84 (1876).

(2) The Federal Food, Drug, and Cosmetic Act Is an Instrument of Public Protection.

The Federal Food, Drug, and Cosmetic Act is designed to protect the public health and pocketbook from adulterated and misbranded foods, drugs, devices, and cosmetics, and it is construed so as best to effectuate that objective. *U. S. v. El-O-Pathic Pharmacy,* 192 F. 2d 62, 75 (C.A. 9, 1951).

VII.
CONCLUSION.

Since Appellant did not establish that California chiropractors are licensed by law to use the ultrasonic devices in question, distribution to such persons would be in violation of the Federal Food, Drug, and Cosmetic Act.

We submit that the judgment of the District Court should therefore be affirmed.

Respectfully submitted,

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APPENDIX A.

Supplemental Stipulation As To Facts.[1]

It is hereby stipulated by the parties to this proceeding, through their respective counsel, as follows:

(1) There are only four colleges of chiropractic in California. Of these four, three colleges do not teach ultrasonic therapy at all, and have never taught it.

(2) In the fourth college, the teaching of ultrasonic therapy was introduced in 1946. This was the first time that ultrasonic therapy was included in the curriculum of any California college of chiropractic. Ultrasonic therapy is now taught as part of 3 different undergraduate courses in that college. The amount of time devoted to ultrasonic therapy in each of these courses varies from a part of a class period to several such periods, as deemed necessary by the class instructor.

(3) Said fourth college of chiropractic has also given some graduate training in ultrasonic therapy. In 1952, ultrasonic therapy was the subject of a seminar in the graduate school comprising a 3 to 12-hour course. In addition, a 2-hour post graduate course in ultrasonic therapy was given there in 1953 and a 3-hour post graduate course in such therapy was given there in 1954.

(4) The curriculum at the various California colleges of chiropractic includes courses in physiotherapy, psychiatry, jurisprudence, and obstetrics.

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[1]This document was designated for printing as part of the printed Transcript of Record. [R. 73, par. 8.] Apparently through an inadvertence, however, it was not printed in that Transcript. We are therefore printing it in full in this Appendix, except for the title of the District Court and of the Cause.

(5) Medical doctors, particularly those who specialize in physical medicine, employ ultrasonic therapy, where medically indicated, as part of their regular treatment of their patients.

(6) Under competent supervision, ultrasonic therapy may be employed safely as adjuvant therapy in the treatment of osteoarthritis and bursitis.

This "Supplemental Stipulation As To Facts" is submitted by the parties in lieu of any affidavits.

Dated: October 1, 1954.

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/s/ Spencer E. Van Dyke,
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/s/ Jack Hildreth,
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Filed October 4, 1954.